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Washington, D.C. 20006
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INTER-AMERICAN DRUG ABUSE
CONTROL COMMISSION

CICAD

Organization of American States

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Secretariat for Multidimensional Security

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**FINAL REPORT
GROUP OF EXPERTS ON PHARMACEUTICAL PRODUCTS**



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**GROUP OF EXPERTS ON
PHARMACEUTICAL PRODUCTS
August 12-14, 2009
Lima, Peru**

**OEA/Ser.L/XIV.4
CICAD/doc.3/09
August 17, 2009
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FINAL REPORT

Executive Summary

During its forty-fourth regular session (November 19-21, 2008) in Santiago, Chile, the Inter-American Drug Abuse Control Commission (CICAD) directed the Group of Experts on Pharmaceutical Products to meet in 2009. The Commission approved the plan of action presented and directed the Group execute this plan and report back during its forty-sixth regular session.

The Group of Experts met in the Asociacion Mutualista de Oficiales de la Policia Nacionl (AMOF) building in Lima, Peru from August 10 to 12, 2009. Mr. Fernando Guzman Coral, Executive Director of DIGEMID in Peru's Ministry of Health chaired this meeting, which included approximately 50 participants from 17 member states (Argentina, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Dominican Republic, Mexico, Panama, Paraguay, Peru, Trinidad and Tobago, United States and Uruguay).

Following the attached schedule of activities, the Group worked on the tasks assigned in the plan of action approved by the Commission during its forty-fourth regular session

The Group of Experts offers the following priority recommendations for the Commission's consideration:

1. That the Commission:
 - **accept** the guide on the control of ephedrine and pseudoephedrine and direct the Executive Secretariat to post it to the CICAD web page
 - **accept** the recommendation to combine the two Groups of Experts to form the **Group of Experts on Chemical Substances and Pharmaceutical Products**
 - **direct** the Group of Experts to continue its work on the issues initiated for consideration and finalizing at the next meeting
 - **accept** the proposed plan of action for the Group of Experts
 - **direct** the Group of Experts to meet during 2010 and implement the plan as proposed, allowing for the consideration of new or emerging issues

I. BACKGROUND

The forty-fourth regular session of the Inter-American Drug Abuse Control Commission (CICAD) took place in Santiago, Chile from November 19 to 21, 2008. During that meeting, the Commission received the report of the Group of Experts on Pharmaceutical Products further to their meeting in Lima, Peru (August 7-8, 2008).

The Commission received the report and approved the Group's proposed plan of action and directed that the Group meet in 2009 to execute this plan. The Government of Peru was then elected chair this meeting.

The meeting took place in Lima, Peru from August 10 to 12, 2009 to execute the tasks defined by the approved plan of action.

II. PROCEEDINGS

A. PARTICIPANTS

MEMBER STATES OF CICAD

Participants to the meeting included approximately 50 representatives from 17 member states (Argentina, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Dominican Republic, Mexico, Panama, Paraguay, Peru, Trinidad and Tobago, United States and Uruguay).

B. SESSIONS AND ORGANIZATION OF THE MEETING

1. OPENING SESSION

The opening session for the meeting of this Group of Experts took place at 14:30 in Lima. Mr. Fernando Guzman Coral welcomed the participants to this Group of Experts meeting.

2. WORKING SESSIONS

A. Presentations

The Group of Experts on Pharmaceutical Products met in four working sessions during which the following presentations were delivered:

- Presentation by the delegation of Peru on the state of use of Methylphenidate

Mr. Fernando Guzman Coral delivered a presentation on the current situation regarding the use of methylphenidate in Peru. This is a pharmaceutical product distributed by prescription used in the treatment of hyperactive deficit disorder in children and narcolepsy. Normally a specialist should be called upon to assess these conditions. The side effects of this drug are significant and can include dependency, various cardio-vascular disorders, and effects on growth among others.

Information available shows that there has been a significant increase in the use of methylphenidate in Peru. Often it is the school teacher who expresses concerns regarding the behavior of a student and suggests the need for this drug. The use of methylphenidate increased by 142% between 2006 and 2008. There is no information to suggest that the pathology requiring this drug has increased in these same proportions. Some companies are advertising that the use of this drug will increase the intellectual development of children.

More recently Peru has issued an alert regarding the problems associated with the excessive or indiscriminant use of methylphenidate. Nonetheless, additional actions are required in Peru to address this growing problem associated with the increased use of methylphenidate.

Participants reacting to the presentation noted a similar problem with increased levels of methylphenidate use in their countries. Some suggested that the increased use may not be associated with the use among children but might also be linked to elevated levels of use by adults for its stimulant properties.

B. Plenary Discussions:

The Group of Experts on Pharmaceutical Products met in plenary session and in smaller working groups to complete the tasks defined by the Group's plan of action contained in the August 2008 report. The Schedule of Activities for the meeting is attached (Annex I). The tasks addressed in plenary included the following:

Control of Ephedrine and Pseudoephedrine (Mexico)

Ephedrine and pseudoephedrine play a critical role in the production of methamphetamine. At the same time these drugs are used in preparations used extensively in the treatment of colds. Narcotraffickers are diverting large quantities of these drugs both in bulk and final form tablets and capsules. The Government of Mexico has implemented strong measures to limit the availability or diversion of these drugs for use in the production of methamphetamine.

Building on Mexico's experience in this regard during the last meeting the Group discussed best practices that member states could implement to control these two drugs. The control of ephedrine and pseudoephedrine presents many challenges for member states and require tailored strategies and approaches to respond to the problem.

Based on the discussion in the Group decided to send the draft back to the working group for further elaboration. The Group also proposed that the draft consider a range of options for action from limitations on distribution to outright banning of these drugs with the steps or actions required in each.

The working group chaired by Mexico reviewed and elaborated the draft. In doing so they were able to finalize their work and present the revised draft for the Group's consideration. This is an issue of great concern to all of the member states represented at the meeting. Following an active exchange the Group finalized the draft guide and presents it for the Commission's consideration and approval

Practical guide for combating counterfeit pharmaceutical products through investigational and increased awareness methodologies (Bahamas/Argentina)

This subject was discussed during the Group's last meeting and assigned to a working group for further elaboration. The delegation of Bahamas was not able attend the current meeting. As such, consideration and finalizing this document will be deferred to the Group's next meeting.

Internet sales of drugs (Canada/US)

The issue of internet sales of drugs has been discussed by the Group during a number of previous meetings. The Group already prepared a guide on this subject.

Building on this experience a working group was formed during the last meeting to prepare a guide to deal with the sale of pharmaceuticals (including counterfeit drugs) over the internet.

The delegation of Canada provided an overview of the guide that was developed by a working group coordinated by Canada and the United States. The Group decided to send this draft back to the working group for further elaboration. The revised draft will be presented for consideration at the Group's next meeting.

Other issues

Historically the Groups of Experts on Chemical Substances and Pharmaceutical Products have met in consecutive sessions. While the presidency of the Groups changes from one group to the other, frequently the composition of the groups remains the same with some few changes. While the subjects discussed in each meeting are specific to the issues of chemical and pharmaceutical control respectively, increasingly the Groups have raised issues that can apply to either.

Based on this increasing blending of issues, the Group of Experts proposed that the two groups be combined into one with a joint mandate. In doing so the new proposed Group must be sure to address issues of concern regarding both chemical substances AND pharmaceutical products during its meeting.

C. Working Groups

Working groups were established to further elaborate draft documents related to issues raised at the last meeting. During the round table introduction of participants, experts also identified the challenges and issues of concern that they are facing with the respect to the control of chemicals. All of these issues served as the basis for discussions during this meeting or for inclusion in the plan of action for future proposed meetings. The working groups considered the following issues:

- **Control of Ephedrine and Pseudoephedrine (Mexico)**
- **Internet sales of drugs (Canada/US)**
- **Guide for increased public-private sector coordination/cooperation to control chemicals (Peru)**

3. PLAN OF ACTION

Further to the discussions in plenary and in the working groups, the Group of Experts has prepared the following plan of action from which the assigned products will be presented when the Group next meets:

Preparation of guides, manuals or other papers associated with the following:

- **Practical guide for combating counterfeit pharmaceutical products through investigational and increased awareness methodologies (Bahamas)**
- **Internet sales of drugs (US)**
- **Internet sales of drugs (Canada and US)**
- **Guide for increased public-private sector coordination/cooperation to control chemicals (Peru)**

4. CLOSING SESSION

The Group of Experts concluded its work at 12:30 on August 14. The Chair thanked the members of the Group for their participation and contribution and closed the meeting.

As the meeting came to an end, the Delegation of Costa Rica expressed its interest in hosting and chairing the next Group's next meeting.

III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

RECOMMENDATIONS TO CICAD IN ITS FORTY-SIXTH REGULAR SESSION:

The Group of Experts on Pharmaceutical Products recommends that the Commission:

1. That the Commission:
 - **accept** the guide on the control of ephedrine and pseudoephedrine and direct the Executive Secretariat to post it to the CICAD web page
 - **accept** the recommendation to combine the two Groups of Experts to form the **Group of Experts on Chemical Substances and Pharmaceutical Products**
 - **direct** the Group of Experts to continue its work on the issues initiated for consideration and finalizing at the next meeting
 - **accept** the proposed plan of action for the Group of Experts
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**MEETING OF THE GROUP OF EXPERTS
CONCERNING PHARMACEUTICAL PRODUCTS**

August 12-14, 2009
Lima, Peru

SCHEDULE OF ACTIVITIES
(Draft)

Wednesday, August 12

13h00 – 14h00	Registration
14h00 – 14h15	Introduction and Review <ul style="list-style-type: none">• Background• Objectives and CICAD Commission expectations• Schedule of work• Proposed work methodology• Status report on Recommendations• Other issues
14h15 – 14h45	Roundtable introductions and identification of issues of concern
14h45 – 15h15	Control of Ephedrine and Pseudoephedrine (Mexico)
15h15 – 15h30	Break
15h30 – 16h15	Follow up on the application of the Guide for the rational use and control (administrative/regulatory) of products containing ephedrine or pseudoephedrine (including natural products) (Mexico)
16h15 – 16h45	Practical guide for combating counterfeit pharmaceutical products through investigational and increased awareness methodologies (Bahamas/Argentina)
16h45 – 17h15	Internet sales of drugs (US)

Thursday, August 13

- 09h00 – 09h30 Presentation by Peru: Increase in prescribing and Use of Methylphenidate
- 09h30 – 12h30 Working Groups
- supply chain control
 - ephedrine and pseudoephedrine
 - disposal of pharmaceutical products
 - trafficking of pharmaceutical products between countries
 - pre-export notification
 - diversion/illicit use diversion of ketamine
 - to be determined based on “roundtable” discussion
- 12h30 – 14h00 Lunch
- 14h00 – 17h00 Working group discussions (con’t)

Friday, August 14

- 09h00 – 10h45 Working Group discussions (con’t)
- 10h45 – 12h15 Working Group Presentations
- 12h15 – 12h45 Conclusions, issues, commitments and recommendations for action by the Expert Group
- 12:45 – 13h15 Closing
- 13h15 Lunch



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**ELEMENTS TO CREATE A NATIONAL STRATEGY TO CONTROL
EPHEDRINE, PSEUDOEPHEDRINE AND PHARMACEUTICAL PRODUCTS
THAT CONTAIN THESE MATERIALS**

INTRODUCTION

Considering the detection of problems derived from the diversion of ephedrine, pseudoephedrine, and pharmaceutical products containing these active ingredients that can be used to make synthetic drugs, it is imperative that States act to create national strategies. The following pages present a series of elements that could eventually be considered for the design and implementation of a national strategy on the subject.

1. Creation of an inter-institutional group that would consider which governmental bodies with jurisdiction over the control of ephedrine, pseudoephedrine, and pharmaceutical products containing that contain these ingredients to include in the decision making process.

- Governmental institutions should participate in said meetings in order to exchange the following information: Prosecutors, customs, health, treatment of addictions and all others that are involved with the subject.

2. Carry out a diagnostic of the situation of ephedrine, pseudoephedrine, and pharmaceutical products containing these ingredients in each country.

- Generate analytical information about:

--Imports, internal consumption and exportation of ephedrine, pseudoephedrine, and pharmaceutical products containing these ingredients.

--Elaboration of public health and epidemiologic study to determine the consumer needs and legal usage of ephedrine and pseudoephedrine.

3. Determination of minimum and maximum limits for importation, exportation, and commercialization of ephedrine, pseudoephedrine, and pharmaceutical products containing these ingredients that can be used in the fabrication of synthetic drugs.

- An analysis of each company that imports such substances.

4. Strengthen the obligatory process of pre-notifications and their responses in the import and export of ephedrine, pseudoephedrine, and pharmaceutical products containing these ingredients.

- Establish permanent points of contact to provide timely reports over modifications.

- Reduce the response times.
- Implement technological tools.
- Inform CICAD about difficulties in the process.
- Establish bi-national agreements to increase the pre-notification of products determined to contain ephedrine and pseudoephedrine.
- Establish proper steps to expedite less than the 15 days established by the JIFE.
- Any other agreements that bilaterally are considered pertinent.

5. Limit the sale of medications that contain pseudoephedrine to pharmaceutical establishments.

- Arrange agreements with the pharmaceutical associations and the distributors so they can only sell certain numbers of boxes of medication per patient.

6. Agree with the pharmaceutical industry to limit the number of units of medication that contain ephedrine and pseudoephedrine and place the medications out of the reach of the public.

- Only sell amounts according to established medical records and do not fill prescriptions that go beyond the given amount in records.
- Stipulate that these types of medications be placed behind the shelf in pharmacies, so that the consumer must ask the vendor for the product. This will reduce sales.

7. Prohibit the import and export of ephedrine, pseudoephedrine, and pharmaceutical products containing these ingredients to intermediaries and wholesalers, limiting permission to the pharmaceutical industry legally established.

- Avoid the commercialization of rhabd material in the domestic market of the country.

8. Define the exclusive points of entry and exit through customs of ephedrine and pseudoephedrine to focus control.

- Analyze, along with the pharmaceutical industry and according to our capacities of customs control, the fixed customs process to authorize international commercialization.

9. Establish a tracking system along the processes of production, distribution, and commercialization of ephedrine, pseudoephedrine, and products that may be possible byproducts of these materials.

- Require the pharmaceutical industry to carry out the necessary controls to be able to identify the route that each load of product is on.

10. Incorporate security measures in the transport and storage of ephedrine and pseudoephedrine in order to avoid its removal.

- Custody
- Vehicles with satellite tracking systems
- Armored vehicles

11. Reclassify medications containing ephedrine and pseudoephedrine establishing the sale of these medications only with a medical prescription.

- According to our legislations, reclassify the medications to a group that requires a medical prescription in order to be bought in pharmacies.

12. Reformulation of the active ingredients in cold medications and substitute ephedrine and pseudoephedrine for ingredients that can't be used for the production of synthetic drugs.

- Present the pharmaceutical industry with the option of using phenylephrine as a substitute for pseudoephedrine.
- Provide as much support and help as possible to companies in order to make these changes (no fees, allow the use of the same commercial name for the product, etc).

13. Evaluate the possibility of prohibiting the import, export, and commercialization of ephedrine and pseudoephedrine in any form or amount of concentration.

14. Implementation of methods in the appropriate disposal of medications that contain ephedrine and pseudoephedrine.

15. Promote the exchange of experiences in controlling ephedrine, pseudoephedrine, and medications that contain these ingredients, on an Inter-American level.